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| 10/532,514 | 04/25/2005 | Christophe Galopin | 102790-131 (30070 US/2) | 7074 |
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| PARFOMAK, ANDREW N. NORRIS MCLAUGHLIN & MARCUS PA 875 THIRD AVE, 8TH FLOOR NEW YORK, NY 10022 | | | EXAMINER ROBERTS, LEZAH | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/532,514 | Applicant(s) GALOPIN ET AL. | |
| | Examiner LEZAH W. ROBERTS | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-17 is/are rejected.
- 7) ☒ Claim(s) 7, 8 and 18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments in the Appeal Brief, filed October 25, 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

In view of the Appeal Brief filed on October 25, 2010, PROSECUTION IS HEREBY REOPENED. New Rejections are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (see the end of the action):

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – Scope of Enablement (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11 and 14-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain specifically disclosed eutectic combinations of menthyl lactate, menthol carboxamide and the solvents propylene glycol and ethanol, does not reasonably provide enablement for eutectic mixtures of menthyl lactate, menthol carboxamide and solvents generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification

Art Unit: 1612

in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

¹ As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is

The invention relates to a composition and making a composition comprising menthyl lactate, menthol carboxamide (WS-3) and a solvent. The components are blended together to make a stable liquid having a higher concentration of menthyl lactate than would be achieved if menthyl lactate was liquefied and added to a solvent without menthol carboxamide, i.e. eutectic mixtures. The relative skill of those in the art is high, that of a PHD or MS. That factor is outweighed, however, by the unpredictable nature of the art. As illustrative of the state of the art, the examiner cites *Cosmetic Dermatology: Products and Procedures* (by Zoe Diana Draelos), the *New World Encyclopedia* and Wang et al. (*Organic Process Research and Development*, 2005).

Draelos discloses the melting point of an active influences solubility. According to solution theory, the lower the melting point, the greater the solubility of a material in a given solvent. The melting point of a material can be lowed by the formation of a eutectic mixture. This mixture of two components which, at certain ratio, inhibits the crystalline process of each other such that the melting point of the two components in the mixture is less than that of each component alone. The type of solvent also plays a role in determining the solubility of a compound in solution (page 64). Different solvents have different characteristics such as the ability to solvate a compound. The *New World Encyclopedia* discloses solvents and solutes can be broadly classified into polar (hydrophilic) and nonpolar (lipophilic). The polarity of a solvent determines what type of compounds it is able to dissolve and with what other solvents or liquid compounds it is miscible. As a rule of thumb, polar solvents dissolve polar compounds best, and

Art Unit: 1612

nonpolar solvents dissolve non-polar compounds best: "like dissolves like." Polar solvents can be further subdivided into polar protic solvents and polar aprotic solvents (page 2 of 5, retrieved 2/11/2011). Solvents, however, are not only used to solubilize a compound. They may also be used for separating a single component from a mixture of components. These mixtures include eutectic mixtures. By adding the proper solvent, one can crystallize one component from the other in these. Wang et al. disclose crystallizing one enantiomer from a mixture of enantiomers by adding the proper solvent. The ee of each component and the eutectic ee will determine the stereoisomer's stability under certain conditions, such as when a solvent. Certain solvents may cause one component of a eutectic mixture to crystallize out of the solution. Thus, in certain cases, the addition of a solvent may cause the solution to have a lower concentration of one component as opposed to a higher concentration as recited by the instant claims. Further menthol carboxamide and menthyl lactate are not very soluble in water, which is encompassed by the recitation of solvent. Therefore it would appear unlikely for a more concentrated mixture of menthyl lactate to occur.

Therefore because of the differences in the nature of different solvents, their variation in their ability to dissolve solutes based on their polarity, and the ability of certain solvents to crystallize one component while leaving the other component in solution, it is difficult to predict if the two cooling agents will be soluble in solvents generally, the extent to which the agents will dissolve in solvents generally, or if the composition will have a higher concentration of one agent in the mixture than it would have if that agent was dissolved alone in a solvent generally.

Although claim 4 recites specific solvents, it also recites “alcohol” generally. The term alcohol encompasses compounds which vary in structure and therefore vary in their ability to solubilize menthyl lactate and menthol carboxamide.

2. The breadth of the claims

The claims are broad insofar as they recite menthyl lactate (which encompasses all its stereoisomers), the menthol carboxamide, and solvents generally. They also are broad insofar as they do not recite the concentration of each component or the concentration range in which each component may be used.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for practicing the claimed invention in its “full scope”. No reasonably specific guidance is provided concerning useful therapeutic protocols for achieving the mixtures comprising menthol carboxamide and menthyl lactate (compositions comprising a more concentrated amount of menthyl lactate), other than those disclosed by the Examples where the amount of menthyl lactate of 55 and 65 parts by weight, menthol carboxamide has concentrations of 14 and 18 parts by weight, and propylene glycol or ethanol have a concentration of 27 or 30 parts by weight, respectively. The latter is corroborated by the working examples.

Art Unit: 1612

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used in all quantities and ratios to yield a composition having a higher concentration of menthyl lactate and would be achieved if menthyl lactate was first liquefied and then added to a solvent and menthol carboxamide as inferred by the claims and contemplated by the specification.

Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its “full scope” a person of ordinary skill in the art would have to engage in undue experimentation, with no reasonable expectation of success.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (WO 99/13734 already of record) in view of H&R (Fescolat Cooling Ingredients 1999). The rejection is maintained in regard to claims 12 and 13, and has been withdrawn in regard to claims 1-11 and 14-18.

Applicant's Arguments

Applicant argues nowhere does Wolf specifically disclose either (a) the specific combination of a menthol carboxamide and menthyl lactate in a solvent as defined by the applicant, or (b) to form a solution having a higher concentration of menthyl lactate in a solvent than could be achieved in the exclusion of menthol carboxamide, by combining melted menthyl lactate with menthol carboxamide and the solvent. Wolf fails to identify solutions specifically containing (or consisting of) menthol carboxamide and menthyl lactate in a non-aqueous solvent, or such specific solutions yield higher solution concentrations of the menthyl lactate in the solvent due to the presence of the menthol carboxamide than could otherwise be attained. Nothing in Wolf illustrates this specific composition, and nothing in Wolf would suggest that improved solubility could be attained upon first melting the menthyl lactate before combining it with the solvent and the menthol carboxamide. Additionally, in view of the fact that menthol carboxamide is insoluble in water, it is submitted that a skilled artisan would also recognize that Wolf's statements that water is generally used would not be applicable for all cooling agents.

The H&R reference does not cure the shortcomings of Wolf, nor render the currently claimed invention as being obvious in view of these combined references. The H&R reference only discloses two options for using Frescolat ML (menthyl lactate), melting menthyl lactate and subsequently adding it to emulsions; and dissolving menthyl lactate in perfume oils, cosmetic oils or glycol solvents. Nowhere does H&R teach or suggest that the Frescolat ML is first melted and then the melted Frescolat ML is subsequently added to a solvent. Nowhere in Wolf or in H&R exists a teaching as to any benefits, viz., increased solubility of methyl lactate leading to a more concentrated

Art Unit: 1612

solution, when it is melted and included in the presence of menthol carboxamide in a solvent, and as such there would be no motivation to produce the specific combination of materials, and/or motivation of the specific process steps to produce a composition as is now claimed. Nor would it be reasonable to presume that specific combination of menthyl lactate and menthol carboxamide (WS-3) in a solvent when formed by the manner outlined in the applicants claimed method would form a eutectic mixture as the Office has suggested. The Su reference is of little relevance to the instant combination.

Examiner's Response

The rejection was withdrawn in regard to claims 1-11 and 14-18 rendering the arguments concerning functional language about a higher concentration of menthyl lactate moot.

The Examiner submits that Wolf suggests the combination of menthol carboxamide with menthyl lactate in a solvent because it teaches the physiological cooling agents may be used in mixtures. Further the reference suggests using cooling agent compositions that do not require menthone or menthol. The reference states: "In a second aspect, the present invention also includes a method for producing chewing gum with an acyclic carboxamide physiological cooling agent or combinations of physiological cooling agents, treated to have a modified release" (page 8, lines 10-13). The reference further states: "By adding a physiological cooling agent to a menthol or mint type flavored chewing gum coating, one can obtain a strong cooling and clean minty flavor, without the higher concentrations of menthol or mint flavors required in

Art Unit: 1612

prior art coatings" (page 12, lines 9-12). The reference further states that the phrase "physiological cooling agent" does not encompass menthol or menthone (page 14, lines 3-8). This suggests that menthol is not always present in the physiological cooling compositions encompassed by the reference. The preferred physiological cooling agents include menthyl lactate and N-substituted p-menthane carboxamide (also known as WS-3 and menthol carboxamide). The solutions of physiological cooling agents, which do not encompass menthol or menthone, comprise a solvent such as water or alcohols (page 25, lines 12-15), which would encompass a non-aqueous solvent as asserted above by Applicant. Further, the claims recite solvent generally and therefore do not limit the claims to non-aqueous solvents. Therefore based on the disclosure, Wolf encompasses a composition consisting of menthyl lactate and menthol carboxamide.

In regard to the H&R reference, the reference is used because it discloses that first melting menthyl lactate is typically performed before adding it to a composition, in the case of the reference an emulsion (which usually comprises a solvent). It further discloses that propylene glycol is used as a solvent for menthyl lactate. Thus it would appear obvious to practice the step of melting menthyl lactate and incorporating it into a composition (which would encompass a solvent comprising menthol carboxamide) considering a manufacturer of menthyl lactate teaches this procedure. It also would have been obvious to use a solvent such as propylene glycol because this is a solvent disclosed by a manufacturer of menthyl lactate. It is also noted that the instant specification only appears to disclose melting menthyl lactate first and then

Art Unit: 1612

incorporating it into a solvent alone or a solvent comprising menthol carboxamide. It does not appear to disclose dissolving menthyl lactate in a solvent or a solvent comprising menthol carboxamide. Therefore it cannot be determined if the melting step is indeed critical to improving the solubility of menthyl lactate while in solution.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (WO 99/13734 already of record).

Wolf discloses compositions comprising cooling flavors. The flavors may comprise about 3% to about 25% by weight of more than one physiological cooling agent. These include menthyl lactate, acyclic carboxamide, N-substituted p-menthane carboxamide and mixtures thereof (page 7, lines 15-22). The preferred cooling agents include WS-3, which encompasses menthol carboxamide of the instant claims, and menthyl lactate (page 18, lines 20-30). The concentration of the physiological cooling agent will depend on the intensity of the physiological cooling agent and the desired cooling effect. The reference also discloses that combinations of cooling agents may have synergistic effects (page 22, lines 5-7). The cooling agents are made into a solution before further processing into a composition. This includes a solution of about 5% to 30% cooling agent. Higher levels may be used if higher temperatures are used.

Art Unit: 1612

Generally water is used as the solvent but other solvents like alcohol should also be used (page 25, lines 8-16).

The reference differs from the instant claims insofar as it does not disclose an exemplified composition comprising the specific mixture of menthol carboxamide and menthyl lactate but does suggest the combination.

Generally, it is *prima facie* obvious to combine two compositions, each of which is taught by the prior art to be useful for same purpose, in order to form a third composition to be used for the very same purpose. The idea for combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. It would have been obvious to have used a combination of menthol carboxamide and menthyl lactate (two physiological cooling agents) in a solvent to include in the compositions of Wolf because the idea of mixing two agents used for the same purpose to make a third compositions flows logically from their having been taught in the prior art and because Wolf suggests the combination.

Allowable Subject Matter

Claims 7, 8 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 7 and 18 recite the specific solvent of propylene glycol and claim 8 recites the specific amount needed to form compositions with higher concentration of menthyl

Art Unit: 1612

lactate. The instant specification disclose examples that support that mixtures of menthyl lactate and menthol carboxamide lead to compositions have higher concentration of menthyl lactate when the solvent is propylene glycol. This would not have been predicted based on the prior art, which teaches mixtures of cooling agents, generally. Therefore, the mixture of menthyl lactate and menthol carboxamide in the specific solvent propylene glycol appears to be nonobvious over the cited prior art.

Claims 1-6 and 9-17 are rejected.

Claims 7, 8 and 18 are objected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

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/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612